

1
2
3
4
5
6 UNITED STATES DISTRICT COURT
7 WESTERN DISTRICT OF WASHINGTON
8 AT TACOMA

9 COLOPLAST A/S,

10 Plaintiff,

CASE NO. C10-227BHS

11 v.

12 GENERIC MEDICAL DEVICES, INC.,

ORDER CONSTRUING
CLAIM TERMS

13 Defendant.

14 This matter comes before the Court pursuant to *Markman v. Westview*
15 *Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), to construe the disputed claim terms of
16 United States Patent No. 6,638,211 (the “‘211 Patent”) and United States Patent No.
17 7,621,864 (the “‘864 Patent”). The Court has reviewed the parties’ opening and
18 responsive briefs, conducted a *Markman* hearing, and considered the remainder of the file
19 and hereby construes the claim terms at issue as stated herein.

21 **I. PROCEDURAL HISTORY**

22 On February 8, 2010, Plaintiff Coloplast A/S (“Coloplast”) filed a complaint for
23 patent infringement against Defendant Generic Medical Devices, Inc. (“Generic”). Dkt.
24 1. Coloplast alleges that Generic is infringing the ‘211 Patent and the ‘864 Patent. *Id.* ¶¶
25 9-17.

26 On March 1, 2010, Generic answered and asserted numerous affirmative defenses
27 including invalidity and unenforceability. Dkt. 17.

1 On January 10, 2011, both parties filed opening claim construction briefs. Dkts.
2 32 (Coloplast) & 35 (Generic). On January 25, 2010, both parties responded. Dkts. 38
3 (Generic) & 39 (Coloplast).

4

II. PATENTS

5 Both the ‘211 Patent and the ‘864 Patent are entitled “Method for Treating Urinary
6 Incontinence in Women and Implantable Device Intended to Correct Urinary
7 Incontinence.” Moreover, both patents contain an introductory paragraph that reads as
8 follows:

9 The invention relates to a method for treating urinary incontinence in
10 women. It also relates to an implantable device intended to correct urinary
11 incontinence in women. The said device is more particularly suited to the
treatment of stress urinary incontinence.

12 *See, e.g.*, ‘211 Patent, col. 1, ll. 16-20.

13

III. DISCUSSION

14

A. Legal Standard

15 It is the obligation of the court to construe as a matter of law the meaning of
16 language used in a patent claim. *Markman*, 52 F.3d at 979. In construing a patent’s
17 claim terms, a court must consider the intrinsic evidence in the record. *See Phillips v.*
18 *AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Intrinsic evidence includes the
19 ordinary and customary meaning of the claim terms, the specification of the patent, and
20 the patent’s prosecution history. *Id.*

21 The ordinary and customary meaning of a term is defined by a person of
22 ordinary skill in the art at the time of the invention. *Id.* The context in which a term is
23 used can be “highly instructive” in resolving the meaning of the term. *Id.* at 1314. For
24 example, if a claim has the term “steel baffle,” it strongly implies that the term “baffle”
25 does not inherently include objects made of steel. *Id.* Other claims in a patent may
26 also provide valuable contextual cues for deciphering the meaning of a term. *Id.* If a
27

1 limitation is present in a dependent claim, then there is a presumption that the
2 limitation is not present in the parent claim. *Id.* at 1314-15.

3 The claims must also be read in light of the specification. *See Markman*, 52
4 F.3d at 979. The specification is always highly relevant to the meaning of a claim
5 term: “Usually, it is dispositive; it is the single best guide to the meaning of a disputed
6 term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If
7 the specification reveals a definition of a claim term that is different from how that
8 term would otherwise be used, then “the inventor’s lexicography governs.” *See*
9 *Phillips*, 415 F.3d at 1316. The court should take care, however, not to import
10 limitations from the specification into the claims. *Id.* at 1323. For example, even if the
11 specification describes very specific embodiments, the claim terms should not be
12 confined to those embodiments. *Id.*

14 The prosecution history of a patent is the last piece of intrinsic evidence that a
15 court should consider when construing the claims of the patent. *Id.* at 1317. The
16 prosecution history provides evidence of how the U.S. Patent and Trademark Office
17 (“PTO”) and the inventor understood the patent. *Id.* A court, however, should be
18 aware that the prosecution history represents the ongoing negotiation between the PTO
19 and the applicant, rather than the final product. *Id.* As such, the prosecution history
20 may lack the clarity of the specification and may not be as useful for claim construction
21 purposes. *Id.* In certain instances, however, the prosecution history may provide
22 guidance of an applicant’s intent to specifically limit the scope of a given claim term.
23 *Id.*

24 Extrinsic evidence is the last category of evidence a court may consider when
25 construing patent claims. *Id.* Such extrinsic evidence includes expert and inventor
26 testimony, dictionaries, and learned treatises. *Id.* On its own, extrinsic evidence is
27 unlikely to be reliable in guiding the court’s claim construction. *Id.* at 1319. Instead,
28

1 extrinsic evidence should be considered in the context of the intrinsic evidence. *Id.* A
2 court may also use extrinsic evidence to determine how a person of ordinary skill in the
3 art would understand the claimed invention. *Id.*

4 Section 35 U.S.C. § 122, ¶ 2 “requires that the scope of the claims be
5 sufficiently definite to inform the public of the bounds of the protected invention,
6 i.e., what subject matter is covered by the exclusive rights of the patent.”

7 *Halliburton Energy Svcs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

8 “Only claims ‘not amenable to construction’ or ‘insolubly ambiguous’ are
9 indefinite.” *Id.* at 1250 (citations omitted). The *Halliburton* court also stated that:

10 Proof of indefiniteness requires such an exacting standard because claim
11 construction often poses a difficult task over which expert witnesses, trial
12 courts, and even the judges of this court may disagree. Nevertheless, this
13 standard is met where an accused infringer shows by clear and convincing
14 evidence that a skilled artisan could not discern the boundaries of the claim
based on the claim language, the specification, and the prosecution history,
as well as her knowledge of the relevant art area.

15 *Id.* at 1249-50 (citations and quotations omitted).

16 With these standards and rules in mind, the Court turns to the disputed terms of the
17 patents in question.

18 **B. Disputed Terms**

19 **1. “Alban fascia”**

20 Coloplast requests that the Court correct the term “Alban fascia” that is contained
21 in the ‘211 Patent’s claim 1 to read “Halban’s fascia.” Dkt. 32 at 25-26. Coloplast
22 concedes “that there is no ‘anatomical structure’ known as the ‘Alban fascia.’” *Id.* at 25.
23 When an error is evident on the face of the patent, a district court may act to correct an
24 error in a patent when (1) the correction is not subject to reasonable debate based on
25 consideration of the claim language and the specification and (2) the prosecution history
26 does not suggest a different interpretation of the claims. *Novo Industries, L.P. v. Micro*
Molds Corp., 350 F.3d 1348, 1358 (Fed. Cir. 2003).

1 In this case, Generic first asserts that the Court may not act to correct the alleged
2 error because the error is not evident on the face of the patent. Dkt. 35 at 12. Generic
3 argues that neither Coloplast nor a previous assignee has ever sought to correct this
4 supposed error. Dkt. 35 at 12. The Court finds this argument irrelevant as to the issue of
5 whether the patent actually contains an error on its face. With regard to this issue, both
6 parties agree that there is no anatomical structure known as the “Alban fascia.” Although
7 Generic claims that “Halban’s facia” is not commonly used, the term does exist in the
8 relevant art. Based on the similarity of the spelling of the terms “Alban” and “Halban,”
9 the fact that both terms are proper nouns, the existence of the term “Halban” in the
10 relevant art, and the fact that the proposed corrected term “Halban” refers to an
11 anatomical structure near the vaginal wall and the urethra, the Court finds that the error is
12 apparent on the face of the patent. The Court will now consider whether it can correct the
13 erroneous term.

14

15 **a. Reasonable Debate**

16 Generic argues that “Coloplast’s proposed correction *is* subject to debate because
17 ‘Alban fascia’ could instead refer to a dissection plane” instead of the anatomical
18 structure Halban’s fascia. Dkt. 38 at 8-10 (emphasis in original). The claim directs the
19 making of an incision “so as to allow the passage of an implant in the form of a tape
20 between the Alban fascia and the periurethral fascias” ‘211 Patent, col. 4:30-34.
21 The specification reads in part as follows:

22 [I]n order to make it easier to fit the tape which acts as an implant, a space
23 is made between, on one hand, the Alban fascia, *the perineal muscular*
plane and the anterior insertion of the puborectal muscle and, on the other
24 hand, the periurethral fascias.

25 *Id.*, col. 2:27-31.

26 Considering the claim language and the specification, the Court finds that the
27 correction is not subject to reasonable debate. First, it is obvious that “Alban facia” refers

1 to a part of the female anatomy near the periurethral fascias so as to allow an implant
2 between it and the periurethral fascias. The specification further describes the referenced
3 area of the female anatomy. Placing an “H” in front of the word “Alban” and making the
4 word possessive are minor errors not subject to debate as to the intended meaning of the
5 reference. Therefore, the Court must determine whether the prosecution history suggests
6 a different interpretation.

7 **b. Prosecution History**

8 With regard to this issue, Generic has only cited a different patent that references
9 the ‘211 Patent application. *See* Dkt. 28 at 8. Finding no prosecution history of the ‘211
10 Patent to the contrary, the Court grants Coloplast’s request to correct “Alban fascia” to
11 “Halban’s fascia.”

12 In light of the correction, the Court also explicitly rejects Generic’s contention that
13 claim 1 of the ‘211 Patent is indefinite because the phrase “Alban fascia” is insolubly
14 ambiguous.

15 **2. “making a median paraurethral incision, practically in the middle third
16 of the urethra, measured from the meatus”**

17 The phrase “making a median paraurethral incision, practically in the middle third
18 of the urethra, measured from the meatus” appears in claim 1 of the ‘211 Patent and
19 claims 8 and 11 of the ‘864 Patent. Coloplast’s proposed construction is “making a
20 midline vaginal incision in the region of the middle third of the urethra measured from the
21 meatus (urethral opening).” Dkt. 32 at 22. Generic argues that the claim is indefinite
22 because the term is inherently inconsistent. *Id.*

23 First, Generic concedes that the “plain language of the phrase ‘making a median
24 paraurethral incision’ means along the side of, or adjacent to, the urethra.” Dkt. 35 at
25 13:18-19. Coloplast requests further clarification by arguing that “‘paraurethral incision’
26 refers to an incision ‘near the urethra.’ . . . meaning to one of ordinary skill of ‘on the
27

1 anterior [upper] vaginal wall, since that is the wall of the vagina that is in the region of
2 the urethra.”” Dkt. 32 at 23. The claim language itself simply does not support this
3 construction of limiting the incision to the vaginal wall. Although the specifications
4 describe the “paraurethral incision” to refer to a “vaginal incision” (‘211 Patent, col. 3:28-
5 46; ‘864 Patent, col. 3:33-47), the Court may not import limitations from the specification
6 into the claim language. *Phillips*, 415 F.3d at 1316. Therefore, the Court construes the
7 phrase “paraurethral incision” to mean “an incision along the side of, or adjacent to, the
8 urethra.”

9 The next phrase the Court must construe is “practically in the middle third of the
10 urethra, measured from the meatus.” Generic argues that “practically in” the urethra
11 should be construed to mean “in” the urethra. Dkt. 35 at 14-15. This construction,
12 however, would defy the ordinary and customary meaning of “practically.” If the
13 inventors intended the incision to be “in” the urethra, they would not have included the
14 modifier “practically.” Therefore, Generic has failed to provide clear and convincing
15 evidence that this phrase is not amenable to construction or is insolubly ambiguous.

16 On the other hand, Coloplast contends that the phrase should be construed as “in
17 the region of the middle third of the urethra measured from the meatus (urethral
18 opening).” The Court finds that Coloplast’s proposed construction of this phrase is
19 consistent with an ordinary and customary meaning of the claim terms.

20 Therefore, the Court construes the phrase “making a median paraurethral incision,
21 practically in the middle third of the urethra, measured from the meatus” to mean “an
22 incision along the side of, or adjacent to, the urethra, in the region of the middle third of
23 the urethra measured from the meatus (urethral opening).”

3. “essentially form a V shape” and “essentially form a V shape, the point of which V passes under the urethra”

Claim 1 of the ‘211 Patent contains the phrase “essentially form a V shape,” and claims 8 and 11 of the ‘864 Patent contain the phrase “essentially form a V shape, the point of which V passes under the urethra.” Generic contends that these claim terms are indefinite. Generic argues that it is

unclear (1) how much slope is allowed in “essentially form[ing] a V shape” (i.e., how much curvature of the branches is allowed); (2) how wide of an angle between the branches of the V there can be while maintaining “essentially a V shape”; and (3) at what point a “V” become a “U” in the context of the claims.

Dkt. 35 at 15. Generic concludes that “one of ordinary skill in the art cannot determine the bounds of what constitutes a ‘V shape’ in the context of the Patents-in-Suit (much less what is ‘essentially’ but not literally a ‘V shape’) and this term is indefinite.” *Id.* at 16.

On the other hand, Coloplast proposes that the Court should construe the phrase to mean “the tape is positioned under the urethra and between the obturator foramen (not led up alongside the bladder to form a U shape).” Dkt. 32 at 26. This construction is primarily based on the portion of the specification that distinguishes the claimed invention from the prior art, which consisted of slings that were inserted into the retropubic space. With regard to this issue, both patent specifications provide as follows:

[C]ontrary to the surgical techniques employed in the state of the art, the tape is not led up alongside the bladder to form a U and thus be situated in close proximity to vital organs, but is on the contrary diverted from the bladder to form a V. Hence, no risk of damaging the bladder, the iliac artery or the small intestine is run. In consequence, it is not necessary to perform cystoscopy during the intervention.

¹ ‘211 Patent, col. 2:19-26; ‘864 Patent, col. 2:21-27.

The Court rejects both parties' positions and finds that the term in question can be construed based upon the ordinary and customary meanings of the words contained therein. First, Generic has failed to provide clear and convincing evidence that the terms are indefinite. While Generic raises plausible questions as to what is "essentially a V

1 shape,” the Court finds that in light of the specification, the scope of the term is
2 “sufficiently definite to inform the public of the bounds of the protected invention.”
3 *Halliburton*, 514 F.3d at 1249.

4 With regard to Coloplast’s proposed construction, the Court is essentially asked to
5 rewrite the phrase in its entirety. The Court finds this request unnecessary as the terms
6 have an ordinary and customary meaning as the term limits the claimed invention to an
7 “implant” that “essentially form[s] a V shape.” Therefore, the Court declines to construe
8 these terms beyond their ordinary and customary meanings.
9

10 **4. “implant,” “elongated implant,” and “tape”**

11 The terms “implant,” “elongated implant,” and “tape” appear in claim 1 of the ‘211
12 Patent and claims 1, 7, 8, and 11 of the ‘864 Patent. Generic proposes that the Court
13 should construe these terms to mean the same thing, which is “a strip of material with
14 tapered ends and a center region that is narrower than the rest of the strip of the material
15 that is suitable for being entrenched in a woman.” Dkt. 35 at 17-20. Generic’s proposed
16 construction violates the rules of claim construction because it would import limitations
17 into the claim terms from specific embodiments described in the specification. For
18 example, the ‘211 Patent provides as follows: “In one advantageous embodiment, the
19 central region of the tape is not as wide as the rest of the tape and this is so as to limit the
20 area of contact in the region” ‘211 Patent, col. 2:66-3:1. Moreover, Generic’s
21 position that the ordinary and customary meaning of the claim terms include the proposed
22 structural limitations is not supported by any intrinsic evidence.
23

24 On the other hand, Coloplast argues that these terms require no construction. The
25 Court agrees and declines to construe these terms beyond their ordinary and customary
26 meanings.
27
28

1 5. **“free ends”**

2 The term “free ends” appears in claim 1 of the ‘211 Patent and claim 8 of the ‘864
3 Patent. Generic proposes that the Court should construe “free ends” to mean “unfastened
4 ends.” Dkt. 35 at 20-22. Coloplast contends that no construction is necessary. Dkt. 32 at
5 21.

6 First, the intrinsic evidence provides little guidance as to the meaning of the term
7 “free.” Figure 1 of the ‘211 Patent refers to “free ends” of the tape and shows ends of a
8 piece of tape that are unattached to any other object. The specification of the ‘211 Patent
9 states that “[t]he free end of the tape is then slipped into the eye of the needle which is
10 pulled back in the same way as before.” ‘211 Patent, col. 1:54-56. Having no
11 prosecution history on this limitation, the Court finds that the intrinsic evidence provides
12 minimal, if any, guidance as to the applicant’s intent of modifying the ends of the tape
13 with the term “free.”

14 With regard to extrinsic evidence, each party has submitted an expert opinion and
15 Generic has submitted the definition of the word “free” according to Webster’s
16 Unabridged Dictionary, Second Edition. Generic’s expert, Dr. George D. Webster,
17 concludes that “one of ordinary skill in art at the time would understand that ‘free ends’
18 refers to the ends of a sling that are not fastened to another object.” Dkt. 36 at 25, ¶ 47.
19 Coloplast’s expert, Dr. Daniel S. Elliot, concludes that a “person of ordinary skill in the
20 art would . . . have understood free ends of the tape to just refer to the ends of the tape.”
21 Dkt. 34-1 at 28. The dictionary provides forty-eight different definitions of the word
22 “free,” none of which contain the word “unfastened.” Dkt. 37-6 at 3. Two of the
23 definitions, however seem applicable to this term: “not held fast; loose; unattached: *to get*
24 *one’s arm free*” and “not joined to or in contact with something else; *the free end of the*
25 *cantelever sagged.*” *Id.* (definitions 14 and 15). In the context of the intrinsic evidence,
26
27

1 the Court finds that these two definitions comport with the ordinary and customary
2 meaning of the term “free” as used in the patent.

3 In making this finding, the Court rejects both parties’ contentions. First, the Court
4 is not convinced that the term “free” is a term of art in the field of female urinary
5 incontinence such that its meaning is different from one that is ordinary or customary.
6 Thus, there is no support for the proposition of construing “free” as “unfastened” and
7 doing so would improperly limit the scope of the claimed invention. Second, Coloplast’s
8 proposal reads the word “free” out of the claim, rendering the term superfluous, which is
9 not the preferred method of claim construction. *Merck & Co. v. Teva Pharm. USA, Inc.*,
10 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the
11 terms of the claim is preferred over one that does not do so.”).

12 Therefore, the Court construes the term “free ends” to mean “ends that are not held
13 fast, loose, unattached or not joined to or in contact with something else.”

14

15 **6. “by pulling the free ends of the tape back through incisions made in the
perineal skin opposite each of the obturator foramen”**

16 Generic proposes that the Court should construe claim 1 of the ‘211 Patent and
17 claims 1, 7, 8, and 11 of the ‘864 Patent to include a phrase that the claimed methods are
18 performed “by pulling the free ends of the tape back through incisions made in the
19 perineal skin opposite each of the obturator foramen.” Dkt. 35 at 24. Generic argues that
20 such language

21 is necessary to make clear that the Patents-in-Suit are limited to the
22 “outside-in” TOT technique and require that the ends of the tape be pulled
23 back through incisions made in the perineal skin opposite each of the
obturator foramen.

24 *Id.* at 26. Generic contends that the Patents-in-Suit must be distinguished from “the
25 ‘inside-out’ TVT-O approach which was developed and patented by Jean De Leval.” *Id.*
26 at 23. Generic, however, fails to provide any authority for the proposition that a district
27 court may, or should, rewrite claim terms in order to distinguish one patent from other
28

1 patented art. Moreover, Generic's argument is based on limitations provided in the
2 description of a specific embodiment of the invention (*see, e.g.*, '211 Patent, col. 3:42-46)
3 and it would be improper for the Court to import those limitations into the claim terms.
4 *Phillips*, 415 F.3d at 1323. Therefore, the Court rejects Generic's proposed construction
5 on this issue.

6 **IV. ORDER**

7 Therefore, it is hereby **ORDERED** that the disputed claim terms of the '211 Patent
8 and the '864 Patent are construed as stated herein.

9 DATED this 21st day of July, 2011.

10
11
12 
13 BENJAMIN H. SETTLE
United States District Judge
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28